and private interests; and acts as the coordinator of the total refugee and entrant resettlement effort for ACF and the Department.

The Discretionary Grants Unit, responsible to the Office of the Director, provides technical administration of ORR discretionary grants; reviews, certifies and/or signs all discretionary grants; assures that all discretionary grants awarded by ORR conform with applicable statutes, regulations, and policies; prepares discretionary grant awards, ensures incorporation of necessary grant terms and conditions, and prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ORR discretionary grant systems and the Department's grant payment systems; and performs audit resolution activities for ORR discretionary grant program.

B. Delete KR.20 Functions, Paragraph C, in its entirety and replace with the following.

C. Division of Community Resettlement directs and manages effective refugee resettlement through the programmatic implementation of grants, contracts and special initiatives associated with national discretionary activity. Provides management of ORR discretionary grants; computes grantee allocations, and monitors grantee expenditures; analyzes financial needs under discretionary grant programs; provides data in support of apportionment requests; and provides technical assistance on discretionary grants operations. The ORR coordinates and provides liaison with the Department and other federal agencies on discretionary grants operational issues and other activities as specified by the Director or required by Congressional mandate.

The Division ensures the quality of medical screening and initial medical treatment of refugees; collects data and performs analyses on the changing needs of the refugee and entrant population; provides leadership to identify data needs and sources, formulates data and reporting requirements; assists states and private agencies on data reporting and the resolution of reporting problems; compiles, evaluates, and disseminates information on the nationwide performance and costs of refugee service programs; responds to unanticipated refugee and entrant arrivals or significant increases in arrivals to communities where adequate or appropriate services do not exist; strengthens the role of ethnic community national or multi-State organizations to promote economic independence among refugees; provides for English Language Training and provides where specific needs have been shown and recognized by the Director for health (including mental health) services, social services, educational and other services.

The Division develops Repatriation plans to make arrangements and approve payments for temporary assistance to certain U.S. citizens and dependents repatriated from foreign countries, and for the hospitalization of certain U.S. Nationals repatriated because of mental illness.

Dated: August 3, 1998.

Olivia A. Golden,

Assistant Secretary for Children and Families.

[FR Doc. 98–21077 Filed 8–5–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0320]

Agency Emergency Processing Request Under OMB Review; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 11, 1998 (63 FR 32102). The document announced an opportunity for public comment on a proposed collection of information that has been submitted to the Office of Management and Budget for emergency processing under the Paperwork Reduction Act of 1995. The notice published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–15484, appearing on page 32102, in the **Federal Register** of Thursday, June 11, 1998, the following correction is made:

1. On page 32103, in the second column, beginning in the first line, ''a nutrient claim or a health claim that is based on an authoritative statement of a scientific body of the Federal Government or the National Academy of Sciences. Under these sections of the act, a food producer that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing'' is corrected to read ''a nutrient content claim or a health claim that is based on an authoritative statement of certain scientific bodies of the Federal Government or of the National Academy of Sciences or any of its subdivisions. Under these sections of the act, a food producer may use such a claim in the labeling of an appropriate product 120 days after a complete notification of the claim is submitted to FDA''.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20956 Filed 8–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biotechnology Manufacturing Grassroots Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Pacific Region, and the Center for Biologics Evaluation and Research (CBER), is announcing the following meeting: Biotechnology Manufacturing Grassroots Meeting. The topic to be discussed is mechanisms and processes through which the agency could potentially increase operational efficiency in relation to both the pre- and post-approval inspection process; improve communication and cooperation among CBER, FDA field offices, and industry representatives associated with biotechnology manufacturing processes; and improve levels of consumer protection.

DATES: The meeting will be held on Tuesday, September 15, 1998, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Los Angeles District Office, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92715.

FOR FURTHER INFORMATION CONTACT: Mark Roh (HFR–PA17), Pacific Regional Office, Food and Drug Administration, 1301 Clay St., suite 1180–N, Oakland, CA 94612, 510–637–3980, fax 510–637–3977, e-mail ''mroh@ora.fda.gov''.

REGISTRATION: Send registration information (including name, title, firm name, address, telephone, and fax number), via fax or e-mail to the contact person by Friday, September 4, 1998.

If you need special accommodations due to a disability, please contact the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Manufacturers in the Pacific Region, who employ biotechnology in the production of FDA regulated products will be able to identify and evaluate opportunities for implementing a partnership approach with FDA. In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnerships Meetings would be held to further the President's initiative. FDA's goal at this meeting is to ''listen'' to concerns and ideas of the biotechnology industry, and to identify next steps for the agency.

There is no registration fee for this meeting. However, registration is required. Early registration is recommended because of space limitations and the need to send information about the meeting format to each registrant. You will be asked to identify the subject area breakout session in which you prefer to participate. To permit the greatest number of firms to attend, each company registering for this meeting should send no more than two representatives.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20955 Filed 8–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0389]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 11, 1998 (63 FR 32102), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on November 30, 1998.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20957 Filed 8–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0519]

Draft Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process.'' This draft guidance is neither final nor is it in effect at this time. The draft guidance includes a flowchart model that could be used by premarket approval application (PMA) holders in their decisionmaking to analyze whether certain changes in a device affect the safety or effectiveness of the device, and therefore, require submission of a new PMA, PMA supplement, alternate submission to a PMA supplement, annual report or documentation in the PMA holders' files on the device.

DATES: Written comments concerning this draft guidance must be received by November 4, 1998.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In January 1997, FDA released a guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' This document was an effort to clarify current practice and FDA's expectations regarding the process used to determine whether a change to a class I or II device or to a class III device for which premarket approval had not yet been required under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)), required submission of a new 510(k).

Class III devices subject to premarket approval requirements under section 515 of the act were not addressed by that document and the PMA regulation, part 814 (21 CFR part 814), provides only general criteria for determining whether a PMA supplement is required for a particular device change. FDA's process of developing specific guidance on submission of PMA supplements coincided with FDA reengineering activities, including the CDRH effort to streamline the PMA supplement process within the context of the existing premarket approval regulation (part 814).

The draft guidance has been developed to aid PMA holders who